## REMARKS

Applicant respectfully requests that the Office withdraw the finality of the Office Action, as Applicant believes the Office Action was improperly made final. According to MPEP Section 706.07(a),

> a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art.

All of the rejections in the Office Action are based on only one reference which is cited for the first time (U.S. Patent No. 5,876,445 to Andersen *et al.* ("Andersen")). Andersen was submitted to the Patent Office by the Applicant in an IDS filed with the application on December 6, 2001. The rejections, therefore, are not based on "information submitted in an information disclosure statement filed under 37 CFR 1.97(c)." Moreover, prior to the instant response, Applicant has amended only claims 1, 9, 15, 22, 27, and 28, and none of the claims dependent therefrom. It is not proper to issue a final rejection based on newly cited art not submitted in an IDS filed under 37 CFR 1.97(c) for any claim not amended by the Applicant. The finality of the Office Action, therefore, should be withdrawn because it includes rejections of non-amended claims based on newly cited art that was not cited in an IDS under 37 CFR 1.97(c).

To the extent that the finality of the Office Action is withdrawn, the Applicant respectfully requests that the Office enter the proposed amendments and consider the following remarks.

After entry of this Amendment and Response, claims 1-28 will be pending. Claims 1-28 have been amended without any intention of disclaiming equivalents thereof. Support for the amendments may be found, for example, in the originally filed claims and on pages 6 to 12 of the specification. It is respectfully submitted that no new matter is added.

To the extent that the Office declines to withdraw the finality of the Office Action, the Office is nevertheless requested to enter the proposed amendments and to consider the following remarks, in view of the fact that the amendments and/or remarks place the case in condition for

allowance. Applicant respectfully submits that the claims, if amended as proposed, will not raise issues of new matter nor present new issues requiring further consideration or search.

Rejection of claims under 35 U.S.C. § 102(b)

Claims 9-14 and 22-26 are rejected under 35 U.S.C. §102(b) as being anticipated by Andersen. Andersen reports on a method for forming, shaping and heat treating a stent for reinforcement of the lumen of peristaltic organs. The stent is formed by knitting. *See, e.g.*, Abstract, Figure 1, and Figures 3-3e. Andersen's stent is formed from a knit cylinder in which the pattern of loops is selected such that the stent accommodates peristalsis without migrating. *See, e.g.*, column 1, lines 60-63. Andersen's stent purportedly is formed from knitted material to accommodate peristalsis of an organ without migrating within the organ. *See, e.g.*, Abstract. Andersen's stent maintains its working length when locally radially compressed to, *e.g.*, accommodate peristalsis, by locally lengthening or shortening due to shifting of the rows of loops relative to each other. *See, e.g.*, col. 1, lines 23-15. To prevent unravelling, a drop of urethane is applied at the ends of the stent. *See, e.g.*, column 10, lines 19-21. As such, it appears as if the entirety of the Andersen stent is a knitted material in a cylindrical configuration. Moreover, Anderson teaches a stent that is not collapsible, but rather provides for reinforcement of the lumen while accommodating peristalsis.

Rejection of claim 9

Independent claim 9 has been amended to recite a stent including, at least, an elongated portion extending from a first point to a second point and a mesh portion extending from the second point. As described above, however, Andersen does not teach a stent having an elongated portion and a mesh portion extending from a point of the elongated portion. Moreover, Andersen does not teach a stent having a mesh portion that is collapsible under radial compression. Rather, Andersen's stent locally lengthens or shortens to accommodate perstalsis and similar bodily movement. Accordingly, Applicant respectfully submits that, for at least these reasons, amended independent claim 9 and all claims dependent therefrom are allowable in view of Andersen.

Rejection of claim 22

Amended independent claim 22 recites a wound coil portion. As described above, however, Andersen does not teach a stent having a wound coil portion. Moreover, Anderson

does not teach a wound coil portion that is collapsible under radial compression. Rather, Anderson's stent locally lengthens or shortens to accommodate perstalsis and similar bodily movement. Accordingly, Applicant respectfully submits that, for at least these reasons, independent claim 22 and all claims dependent therefrom are allowable in view of Andersen.

Accordingly, Applicant respectfully requests that the rejection of claims 9-14 and 22-26 be reconsidered and withdrawn.

Rejection of claims under 35 U.S.C. § 103(a)

Claims 1-8, 15-21, 27, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Andersen.

Rejection of claims 1 and 27

Amended independent claims 1 and 27 each recite a stent – or providing a stent – having an elongated portion, a retention portion extending from a first end of the elongated portion, and a mesh portion extending from a second end of the elongated portion, the mesh portion being collapsible under radial compression. As described above, however, Andersen reports on a cylindrical stent formed by knitting and does not teach or suggest a stent having an elongated portion, a retention portion extending from a first end of the elongated portion, and a mesh portion extending from a second end of the elongated portion. In addition, Andersen does not teach or suggest a stent having a mesh portion that is collapsible under radial compression. Rather, Andersen's stent locally lengthens or shortens to accommodate perstalsis and similar bodily movement.

Moreover, not only does Andersen not teach or suggest a stent having an elongated portion, a retention portion extending from a first end of the elongated portion, and a mesh portion extending from a second end of the elongated portion and being collapsible under radial compression, but also Andersen does not provide motivation to modify its stent to arrive at the device recited in amended independent claims 1 and 27. An elongated portion added to the knitted stent of Andersen possibly would not allow for local lengthening and shortening to accommodate peristalsis as would the knitted portion of the stent. Combining the knitted portion with an elongated portion may, therefore, hinder the attainment of Andersen's purported objective of accommodating peristalsis. Furthermore, as mentioned above, Andersen's stent apparently relies on the properties of the knitted material to maintain the stent in place. As such, Applicant

believes that one skilled in the art would not add a retention structure to the stent of Andersen that purportedly is already designed not to migrate.

Accordingly, Applicant respectfully submits that, for at least these reasons, amended independent claims 1 and 27 are patentable and that claims 2-8, which depend directly or indirectly from claim 1, also are patentable as dependent from an allowable base claim.

Rejection of claims 15 and 28

Amended independent claims 15 and 28 each recite a stent – or providing a stent – having an elongated portion, a retention portion extending from a first end of the elongated portion, and a coil portion extending from a second end of the elongated portion and including a wound coil, the wound coil being collapsible under radial pressure. As described above, Andersen reports on a stent formed from a knitted cylinder in which the pattern of loops is selected such that the stent accommodates peristalsis without migrating and does not teach or suggest a stent having an elongated portion, a retention portion extending from a first end of the elongated portion, and a coil portion extending from a second end of the elongated portion and including a wound coil. In addition, Andersen does not teach or suggest a stent having a wound coil portion that is collapsible under radial compression. Rather, Andersen's stent locally lengthens or shortens to accommodate perstalsis or similar bodily movement.

Moreover, not only does Andersen not teach or suggest a stent having an elongated portion, a retention portion extending from a first end of the elongated portion, and a coil portion extending from a second end of the elongated portion and including a wound coil collapsible under radial pressure, but also Andersen does not provide motivation to modify its stent to arrive at the device recited in amended independent claims 15 and 28. An elongated portion added to the knitted stent of Andersen possibly would not allow for local lengthening and shortening to accommodate peristalsis as would the knitted portion of the stent. Combining the knitted portion with an elongated portion may, therefore, hinder the attainment of Andersen's purported objective of accommodating peristalsis. Furthermore, as mentioned above, Andersen's stent apparently relies on the properties of the knitted material to maintain the stent in place. As such, Applicant believes that one skilled in the art would not add a retention structure to the stent of Andersen that purportedly is already designed not to migrate. Similarly, as Andersen's stent apparently relies on the properties of the knitted material and pattern of loops to accommodate peristalsis

and retain the stent in place, substituting a coil for the knitted material possibly would hinder attainment of these purported objectives.

It is respectfully submitted, therefore, that Andersen fails to teach or suggest any of the elements of the stent recited in amended independent claims 15 and 28 and also provides no motivation for its modification to arrive at the device recited in amended independent claims 15 and 28. Accordingly, Applicant respectfully submits that, for at least these reasons, amended independent claims 15 and 28 are patentable and that claims 16-21, which depend directly or indirectly from claim 15, also are patentable as dependent from an allowable base claim.

Accordingly, Applicant respectfully requests that the rejection of claims 1-8, 15-21 27, and 28 be reconsidered and withdrawn.

## CONCLUSION

In view of the foregoing, Applicant respectfully submits that all claims are now in condition for allowance.

Respectfully submitted,

Date: December 22, 2003
Reg. No.: 44,381

Natasha C. Us
Attorney for Applicant
Testa, Hurwitz & Thibeault, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel. No.: (617) 310-8327
Fax No.: (617) 248-7100

2727505-1